Appendix E

DCP Guidelines and Serious Adverse Event Form

APPENDIX E
DCP GUIDELINES AND SERIOUS ADVERSE EVENT FORM

Appendix E
Adverse Event Reporting Chart:
Summary of Investigator's Obligations for Reporting Adverse Events in Phases I, II, III Clinical Trials to the National Cancer Institute, Division of Cancer Prevention (DCP)

Reaction	*Reporting Obligation*
a. ALL SERIOUS ADVERSE EVENTS Any adverse event (AE) occurring at any dose that: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse event when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.	REPORT BY PHONE TO DCP WITHIN 24 HOURS.[1] (written report to follow within 48 hrs[2])
b. ALL ADVERSE EVENTS (SERIOUS, NON-SERIOUS)[3]	REPORTED in the AE CRF and Progress Reports.

[1] Telephone number available 24 hours daily: 301-496-8563 (Recorder after hours); FAX: 301-402-0553 or 301-594-2943.

[2] Report to:

Medical Monitor (as specified in the protocol)
DCP/National Cancer Institute/NIH
Executive Plaza North, Suite 201
9000 Rockville Pike
Bethesda, MD 20892
For Express (*e.g.*, Federal Express, DHL, Airborne) or Hand Delivery
Executive Plaza North, Suite 201
6130 Executive Blvd.
Rockville, MD 20852

[3] A list of all known toxicities can be found in the Investigator's Brochure, package insert, or other material provided by NCI.

NCI Contract/Grant No._____ Study Subject No._____
IRB Protocol No. _____

NCI, DIVISION OF CANCER PREVENTION (DCP)
SERIOUS ADVERSE EVENT FORM

REQUIRED FIELDS ON ALL REPORTS

Today's Date:	Sponsor: NCI, DCP	Study (Indication):
Drug under Investigation:	IND No.:	

A. Study Subject Information

1. Patient Initials	2. Date of Birth: _____ (Month/Day/Year)	3. Weight at Time of Event: _____ [ ] kg [ ] lbs. [ ] not available	4. Height at Time of Event: _____ [ ] cm [ ] ft [ ] not available

B. Event Information

[ ] Initial Event Report [ ] Follow-up	Gender: (circle one) M F	Dose at Event:
Event Onset Date: (Month/Day/Year)	Primary Event (diagnosis):	
Event Approx. Time: (Indicate A.M./P.M.)		
Event Occurred at:		
Duration of Drug Exposure at Event:	Primary Treatment Approx. Time (A.M./P.M.): Primary Treatment of Event:	
Attending Physician (Name): Phone/FAX No.: Hospital/Clinic: Address:		
Describe Event (if applicable, include dates of hospitalization for event):		
Form Completed by: (Print Name) _____ Title_____ Investigator Signature _____ Date _____ Phone No. _____ (Month/Day/Year)		

NCI Contract/Grant No._____ Study Subject No._____
IRB Protocol No. _____

ALL FIELDS APPEARING IN THE FOLLOWING PAGES (C-F) MUST BE COMPLETED FOR THE INITIAL REPORT; THEREAFTER, FILL IN ONLY SECTIONS THAT PROVIDE ADDITIONAL/ CORRECTIVE INFORMATION.

C. Site information

1. Investigator Name

2. Address

D. Suspect Medication(s)

1. Study Design: [ ] Blind [ ] Open/Unblind

Possible Dose (*e.g.*, 300 mg) _____ Frequency (*e.g.*, qd) _____ Route (*e.g.*, po)_____

2. Study Drug Formulation (*e.g.*, tablet, solution)

Lot No. (If known)

3. Start Date of Study Drug (Month/Day/Year):

4. Was blind broken due to event? [ ] No [ ] Yes [ ] NA

5. Was Study Drug stopped/interrupted/reduced in response to event? [ ] No [ ] Yes

>> If yes, complete a-e:

a. If stopped, specify date study drug last taken: _____ [ ] NA
(Month/Day/Year)

b. If reduced, specify: New dose _____ Date reduced _____ [ ] NA
(Month/Day/Year)

c. If interrupted, specify total number of days not given: _____ [ ] NA

d. Did event abate after study drug was stopped or dose reduced? [ ] NA [ ] Yes [ ] No

e. Did event reappear after study drug was reintroduced? [ ] NA [ ] Yes [ ] No

6. Was patient taking any other medications concomitantly at the time of the event?[ ] No [ ] Yes >> If yes, complete below.
(DO NOT LIST DRUGS USED TO TREAT EVENT)

Drug Name Doses (units, frequency, route, indication for use)	Start Date			Stop Date or mark (X) if continuing			
	Month	Day	Year	Month	Day	Year	(X)

(continue on a separate sheet if necessary)

E. Adverse Event

1. Relevant Laboratory/Diagnostic Tests [ ] No tests performed

Date	Test	Results	
		Actual Value	Normal Range
Month Day Year			

(continue on a separate sheet if necessary)

2. Relevant Medical History, including preexisting conditions (*e.g.*, allergies, pregnancy, smoking & alcohol use, hepatic/renal dysfunction, medical/surgical history, *etc.*)

Date (if known) Diseases/Surgeries/Treatment

(continue on a separate sheet if necessary)

3. **NCI Toxicity GRADE of the Event** (use NCI Common Toxicity Criteria): [ ] 0 [ ] 1 [ ] 2 [ ] 3 [ ] 4
If not gradable by NCI CTC, check one of the following: [ ] Mild (Causing no limitation of usual activities)
[ ] Moderate (Causing some limitation of usual activities) [ ] Severe (Causing inability to carry out usual activities)

4. Why Serious?
[ ] Results in death [ ] Is life-threatening [ ] Requires inpatient hospitalization or prolongation of existing hospitalization
[ ] Results in persistent or significant disability/incapacity [ ] Is a congenital anomaly/birth defect
[ ] Other, specify:_____

5. Outcome of Event (at time of report)
[ ] Resolved-date: _____ [ ] Improved [ ] Unchanged [ ] Worse [ ] Not available
(Month/Day/Year)
[ ] Fatal-date of death: _____ Autopsy performed? Y N
(Month/Day/Year) (circle one)
Cause of death: _____ (please attach death certificate and autopsy report, if applicable)

6. Investigator's opinion of the relationship between the event and the study drug (If more than one event is being reported, list secondary events and corresponding relationship to study drug in the comments section below.) Check applicable box:

[ ] Not related [ ] Unlikely [ ] Possible [ ] Probable [ ] Definite

7. Was this event reported by the Investigator to (check all that apply): [ ] IRB [ ] Manufacturer/Distributor
[ ] Other Investigators participating in this study, if checked, please list names and institutions

_____
_____
_____
_____

F. Comments/Clarifications:

FOR NCI USE ONLY

1. Date NCI notified of event (Month/Day/Year):

2. Medical Monitor Review:

Medical Assessment of Event (including drug relationship and expectancy):

Is this an FDA reportable (7 calendar days) event? [ ] Yes [ ] No

Is this an FDA reportable (15 calendar days) event? [ ] Yes [ ] No

>> If No, specify reason:_____

Is more information expected? [ ] Yes [ ] No

>> If Yes, specify:_____

Is this event to be communicated to other NCI contractors using this investigational drug? [ ] Yes [ ] No

>> If Yes, how? By telephone (attach a TC Form): [ ] Yes, attached TC Form [ ] No

Other (FAX, mail, e-mail, *etc.*): [ ] Yes, attached a copy of the correspondence [ ] No

Medical Monitor: Print name _____ Signature _____ Date _____